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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,867	09/05/2003	Robert A. VanTassel	593/CIP2DIV	7301

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT PAPER NUMBER

3731

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary**Application No.**

10/655,867

Applicant(s)

VANTASSEL ET AL.

Examiner

Michael G. Mendoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-16 is/are rejected.
- 7) ☒ Claim(s) 6 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 27 October 2004 have been fully considered but they are not persuasive.

2. In response to applicant's argument that the membrane fits over the ostium of a left atrial appendage, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The apparatus of Lesh et al. comprises the claimed structural limitations; a membrane having an outer periphery with a dimension larger than a corresponding dimension; and securement means. As seen in figure 5 of Lesh et al., the actual diameter of the device is larger than the diameter of the cavity. Furthermore, in figure 5 the periphery of the membrane is in contact with an atrial wall. The atrial wall being any tissue that surrounds the cavity.

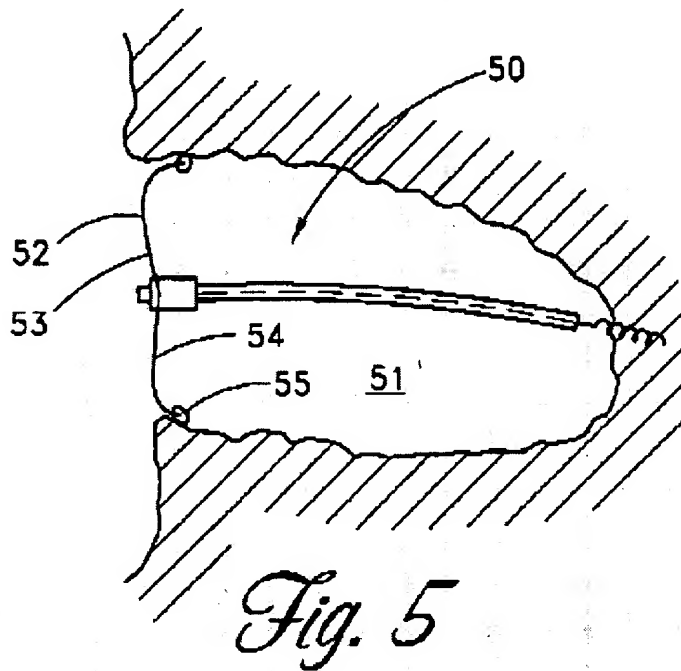
3. In response to applicant's arguments, the recitation "for attachment over an ostium" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the

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process steps or structural limitations are able to stand alone. See *In re Hirao*, 535

F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88

USPQ 478, 481 (CCPA 1951). The device of Lesh et al. is fully capable of attachment over an ostium.



Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claims 1-5 and 11-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Lesh et al. 6152144.

Lesh et al. teaches an apparatus for attachment over an ostium of a left atrial appendage in a patient, comprising: a membrane 53 having an outer periphery with a dimension larger than a corresponding dimension of an ostium; and securement means (figs. 1, 3-7, 11, and 12); wherein the securement means is located between the outer periphery of the member and the atrial wall surrounding the ostium; wherein the securement means comprises an adhesive (col. 2, lines 13-17); wherein the adhesive is cyanoacrylate (col. 4, lines 62-64); wherein the securement means comprises a plurality of engagement member attached to the member at a plurality of location about the outer periphery of the membrane (fig. 6 and 7); wherein the securement means comprises a structure configured to extend distally from the membrane into the ostium (fig. 12); wherein the securement means is configured for enlargement in response to expansion of an expansion structure located in an interior portion of the securement means (col. 9, lines 29-33); wherein the securement means is resiliently biased in an enlarged configuration for engagement with the interior wall of the left atrial appendage and may be constrained in a reduced size configuration for installation in the left atrial appendage (fig. 11); wherein the membrane has a permeable structure which allows blood to flow through the membrane but substantially inhibits thrombus from passing therethrough (col. 1, lines 64-67 thru col. 2, lines 1-6); wherein the member has an impermeable structure which substantially inhibits thrombus and blood from passing therethrough

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(col. 2, lines 39-41); wherein the securement means comprises membrane supporting structure attached to the outer periphery of the membrane (col. 7, lines 54-64).

Allowable Subject Matter

6. Claims 6 and 7 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 6 depends on dependant claim 5. Claim 7 depends on claim 6.

Terminal Disclaimer

7. The terminal disclaimer filed on 27 October 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. 6,652,556 B1 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn Dawson can be reached on (571) 272-4694. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM



GLENN K. DAWSON
PRIMARY EXAMINER